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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,820	10/05/2001	Dean A. Falb	7853-0248	2738

7590 11/03/2004

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EXAMINER	
BURKHART, MICHAEL D	
ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/970,820	FALB ET AL.	
	Examiner	Art Unit	
	Michael D. Burkhart	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *67-102* is/are pending in the application.

4a) Of the above claim(s) *100-102* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *67-99* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 67-102 are pending. In a response (dated 9/27/2004) to a restriction requirement applicants elect Group I, claims 67-99, without traverse. Claims 100-102 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Priority

This application, filed 10/5/2001 claims benefit of 09/176,330, filed 10/22/1998, abandoned 2/25/2002, which is a CIP of 08/386,844, filed 2/10/1995, now U.S. patent 6,156,500, issued 12/5/2000. The claimed invention recites antibodies specific for rchd523, which requires disclosure of the amino acid coding sequence. No coding sequence of rchd523 was disclosed in the 08/386,844 application, only a partial sequence of the 3' untranslated region. The full-length sequence of rchd523 was not disclosed until the 09/176,330 application. Hence, provided applicant addresses the issue set forth below, the invention is granted a priority date of 10/22/1998.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior

nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Specification

The specification is objected to under 37CFR 1.52(b), which requires that the pages of the specification be numbered starting with "1". Pages i-iv of the specification of the specification do not conform with the arrangement of the specification according to MPEP 608.01(a). The "Table of Contents" must be deleted because the page numbers referred to for each section are irrelevant when a patent issues.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 67-69, 76-78, 92-94 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims read on a product of nature, that is naturally occurring antibodies against a naturally occurring human protein. The antibodies are not recited as isolated or recombinant and thus read on naturally occurring antibodies in a human body.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 75-91, and 99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 75, 83, 91 and 99 recite a composition comprising an rchd523-specific antibody and another therapeutic antibody. This is unclear because a first therapeutic antibody is implied, but none has been disclosed. It cannot be determined if rchd523 antibodies are the other "therapeutic antibody" or if there is an additional "therapeutic antibody" in the claimed composition. The metes and bounds of the claimed subject matter are unclear.

Claims 75, 83, 91 and 99 recite a composition comprising an rchd523-specific antibody and another therapeutic antibody. It cannot be determined if this composition is meant to be a conjugate of two antibodies (i.e. a single molecule), or two distinct, un-conjugated antibodies present in a mixture. The metes and bounds of the claimed subject matter are unclear.

Claims 76 and 84 (and dependent claims) are unclear because they recite "and/or analogs thereof" of the rchd523 protein. It is unclear how close to the original rchd523 sequence an analog might be. The metes and bounds of the claimed subject matter are unclear.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 76-91 and 99 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim a composition comprising an rchd523-specific antibody and another therapeutic antibody. Applicants also claim an antibody specific for the extracellular domains and/or analogs thereof of rchd523, and the analog may be an Ig-tailed soluble fusion protein. Applicants disclose the sequence of the rchd523 gene and certain diseases circumstantially linked to rchd523. The claims read on a very large genus of therapeutics and antibodies that comprise any antibody with therapeutic potential along with antibodies to a protein with an unspecified relatedness to rchd523 (an analog). The definition of an analog is taken to be a molecule with a similar function and different genetic origin (American Heritage dictionary). The written description requirement for a genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function, or by a combination of such identifying characteristics, sufficient to show that applicant was in possession of the claimed invention.

In the instant case, applicants only disclose the nucleic acid and deduced amino acid sequence of rchd523, then classify rchd523 as a G-protein coupled receptor (GPCR) based on

homology. The rchd523 sequence was identified as being upregulated upon shear stress to certain cell types. Applicants do not disclose the function or analogs of rchd523, its ligand, antibodies to rchd523, or the claimed therapeutic antibodies. The prior art (Owman et al., see enablement rejection below) discloses a protein, CMKRL2, identical to rchd523 except for a Q to R amino acid change at residue 138. This degree of conservation indicates an allele, not an analog. While both molecules are identified as GPCRs by homology, neither the ligand or signaling pathway (function) of either is known. If the function of rchd523 is unknown, how can there be a basis for one skilled in the art to envision analogs of and therapeutic antibodies compatible with rchd523? Hence, there is no structural/functional basis provided to envision other embodiments such as rchd523 analogs and therapeutics. Applicants claim rchd523 analogs and therapeutic antibodies by function only, without a correlation between structure and function. The prior art does not compensate for the lack of description of specific examples of rchd523 analogs and therapeutic antibodies suitable as claimed. The lack of disclosure and broad genus regarding the claimed analogs and therapeutic antibodies would require the skilled artisan to conclude that the example presented by the applicants are not sufficient to describe the claimed genus.

Claims 67-99 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art

without undue experimentation (*United States v. Telectronics,* Inc. 8 USPQD2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is required is a conclusion reached by weighing several factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQQ2d 1400 (Fed. Cir. 1988) and include the following:

Unpredictability of the art. The claims recite an antibody that binds immunospecifically to rchd523. Because it is not defined otherwise in the specification, "immunospecifically" is taken to mean an antibody that binds to rchd523 only. However, Owman et al. (Biochem. Biophys. Res. Comm., Vol. 228: pgs. 285-292) disclose a protein, termed CMKLR2, that differs from the disclosed rchd523 sequence by one residue, a Q to R amino acid change at residue 138. Therefore, to discriminate between these two proteins, the claimed antibody would have to recognize an epitope that comprised this Q to R change. The art concerning production of antibodies to a specific epitope is unpredictable. For antibody production, the protein antigen (rchd523 in this case) is used to immunize animals, which produce a range of antibodies specific for different epitopes on the antigen, based on (in a simplified explanation) the genetic library of the animals B-cell receptors, epitope presentation, and the presence of helper T-cell epitopes within the antigen. The result is a set of antibodies to distinct epitopes throughout the protein, the location of which is completely unpredictable and which may or may not include, in the instant case, the desired specificity for the Q to R change. Due to the conservation at the amino acid level between these proteins, an antibody that recognizes any other epitope would recognize both proteins.

State of the art. The state of the art regarding the production of antibodies to a specific epitope is poorly developed. The development of such methods and antibodies would have to be done empirically.

Number of working examples. Applicants have provided no working examples of antibodies specific for rchd523, let alone an antibody that can distinguish between rchd523 and CMKRL2.

Amount of guidance. Applicants provide no direction on how to produce the claimed antibody. The specification requires the skilled artisan to practice trial and error experimentation with different antigens and vaccination methods to produce the claimed invention.

Scope of the invention. The claims are narrow in nature, reading on an antibody that recognizes only a unique protein.

Nature of the invention. The invention involves the unpredictable art of producing an antibody that can distinguish between two highly conserved proteins.

Level of skill in the art. While the level of skill in the art is high, the unpredictability of the art, lack of guidance, lack of working examples and poorly developed state of the art would require that undue and excessive experimentation would have to be conducted by the skilled artisan in order to practice the claimed invention.

Given the above analysis of the factors which the courts have determined are critical in determining whether a claimed invention is enabled, it must be considered that undue and excessive experimentation would have to be conducted by the skilled artisan in order to practice the claimed invention.

The invention appears to employ novel biological materials (claims 92-99), specifically the plasmid pFCHD523 deposited with the ARSCC as accession No. B-21458. Since the biological materials are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological materials are not so obtainable or available, a deposit of the biological materials may satisfy the requirements of 35 U.S.C. § 112. The specification does not disclose a repeatable process to obtain the biological material and it is not apparent if the biological materials are readily available to the public. It is noted that Applicant has deposited the biological materials, but there is no indication in the specification as to public availability. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon an issuance of patent, would satisfy the deposit requirement made herein. If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, Applicant may provide an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R. §§ 1.807); and

(e) the deposit will be replaced if it should ever become unviable.

Applicant's attention is directed to M.P.E.P. § 2400 in general, and specifically to §2411.05, as well as 37 C.F.R. § 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." The specification should be amended to include this information, however, Applicant is cautioned to avoid the entry of new matter into the specification by adding any other information. Finally, Applicant is advised that the address for the ATCC has recently changed, and that the new address should appear in the specification. The new address is:

American Type Culture Collection

10801 University Boulevard

Manassas, VA 20110-2209

Conclusion

No claims are allowed.

The closest prior art is exemplified by Owman et al. (cited above) who teach the CMKRL2 protein, which shares a remarkable conservation (one amino acid difference) with the claimed rchd523. However, Owman et al. do not teach antibodies to the CMKRL2 protein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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